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A Randomized Trial of Intravenous Labetalol Versus Oral Nifedipine in Acute Blood Pressure Control in Hypertensive Emergencies of Pregnancy

Kiran Oswal[1], Uma Mahesh Sindoor[2]

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ABSTRACT

Background: Hypertension in pregnancy, called a disease of degree is more of a sign than a disease by itself. Hypertensive disorders of pregnancy, including chronic hypertension, with or without superimposed pre-eclampsia/eclampsia, gestational hypertension, HELLP syndrome, pre-eclampsia with or without severe features or eclampsia present a significant risk of morbidity to both mother and fetus. Effective pharmacologic therapy modifies the course of the disease. The effective use of anti-hypertensive therapy should be based on well designed controlled clinical trials and the experience of the clinician with the drugs. Hypertensive disorders complicate 5-10% of all pregnancies worldwide.[1] Dangerous hypertension is a harbinger of cerebrovascular accidents, eclampsia, hypertensive encephalopathy and other end organ damage with a poor perinatal outcome.[2]

Methods: This prospective randomized double blind comparative clinical trial with randomization done using computer generated numbers study was carried out in 100 cases being brought in OBG department of AL Ameen Medical College, Bijapur, from July 2023 to December 2023. A detailed data of sociodemographic profile, general examination and obstetric examination were carried out. The pregnant women were randomized with computer generated numbers into two groups to receive either oral nifedipine or intermittent intravenous labetalol injections.

Results: There is no significant difference in the parity of both the groups. Majority of the patients constituting 80% of group A and 58% of group B were primigravida. 69% enrolled in the study were primigravida. There is a higher incidence of pre-eclampsia in the first pregnancy. The majority of the patients had gestational age of 34 to 36 weeks constituting 48% on the whole with 50% and 46% respectively in group A and B. The recruited patients did not significantly differ in gestational age.

Keywords: Intravenous labetalol; Oral nifedipine; Hypertensive emergencies.

Author's Affiliation: [1]Associate Professor, [2]Senior Resident, Department of Ostetrics and Gynecology, Al Ameen Medical College, Vijaypura, Karnataka 586108, India.

Corresponding Author: Uma Mahesh Sindoor, [2]Senior Resident, Department of Ostetrics and Gynecology, Al Ameen Medical College, Vijaypura, Karnataka 586108, India.

E-mail: buzz2lohith@gmail.com

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INTRODUCTION

Hypertension in pregnancy, called a disease of degree is more of a sign than a disease by itself. Hypertensive disorders of pregnancy, including chronic hypertension, with or without superimposed pre-eclampsia/eclampsia, gestational hypertension, HELLP syndrome, preeclampsia with or without severe features or eclampsia present a significant risk of morbidity to both mother and fetus. Effective pharmacologic

therapy modifies the course of the disease. The effective use of anti-hypertensive therapy should be based on well designed controlled clinical trials and the experience of the clinician with the drugs. Hypertensive disorders complicate 5-10% of all pregnancies worldwide.[1] Dangerous hypertension is a harbinger of cerebrovascular accidents, eclampsia, hypertensive encephalopathy and other end organ damage with a poor perinatal outcome.[2] Labetalol was studied for its use in treatment of hypertensive urgencies in the general population. The smooth onset of action with minimal change in cardiac output and heart rate makes it a unique drug in the management of hypertensive emergency in pregnancy. Nifedipine has been evaluated for its immediate onset of action and ease of administration and no reported adverse effects on the mother or the fetus and on the course of labour. Hence this study was carried out to compare the pharmacodynamics of intravenous labetalol and oral nifedipine in patients with severe hypertension and to compare the maternal and fetal outcomes and adverse effects of both the drugs.

MATERIALS AND METHODS

This prospective randomized double blind comparative clinical trial with randomization done using computer generated numbers study was carried out in 100 cases being brought in OBG department of AL Ameen Medical College, Bijapur, from July 2023 to December 2023. A detailed data of sociodemographic profile, general examination and obstetric examination were carried out. The pregnant women were randomized with computer generated numbers into two groups to receive either oral nifedipine or intermittent intravenous labetalol injections.

STATISTICAL ANALYSIS

The data was analyzed using SPSS software version 20. Differences in categorical and continuous data were assessed using the Chi square test and Student 't' test, respectively. The tests were two sided. The statistical test is considered significant if the calculated p-value is less than 0.05.

RESULTS

A total of 100 cases were included in this study

Table 1: Parity wise distribution of study subjects

Parity	Group-A Labetalol		Group-B Nifedipine		Total 100
	50	%	50	%	
Primi	40	80%	29	58%	69%
G2	6	12%	13	26%	19%
G3	2	4%	6	12%	8%
G4	2	4%	2	4%	4%
χ 2 =7.465 Degree of freedom = 3 P= 0.058 > 0.05					

Parity was comparable in group A and group B. There is no significant difference in the parity of both the groups. Majority of the patients constituting 80% of group A and 58% of group B were primigravida. 69% enrolled in the study were primigravida. There is a higher incidence of pre-eclampsia in the first pregnancy

Table 2: Gestational age distribution of study subjects

Gestational Age	Group-A Labetalol		Group-B Nifedipine		Total 100
	50	%	50	%	
24 Weeks	1	2%	2	4%	3%
25-28	8	16%	7	14%	15%
29-33	21	42%	15	30%	36%
34-36	25	50%	23	46%	48%
37 Weeks	5	10%	3	6%	8%
χ 2 = 1.363 Degree of freedom = 4 P = 0.851 > 0.05					

The majority of the patients had gestational age of 34 to 36 weeks constituting 48% on the whole with 50% and 46% respectively in group A and B. The recruited patients did not significantly differ in gestational age.

Table 3: Systolic blood pressure distribution of study subjects

Systolic Blood Pressure	Group-A Labetalol		Group-B Nifedipine		Total 100
	50	%	50	%	
160-169 mmHg	25	50%	18	36%	43%
170-179 mmHg	14	28%	26	52%	40%
≥ 180 mmHg	11	22%	6	12%	17%
T= 0.477 Degree of freedom = 104 0.635 > 0.05 Not Significant					

The baseline systolic blood pressure of the patients recruited in both the groups did not differ significantly. The mean systolic blood pressure in intravenous labetalol group was 168 mmHg whereas it was 171 mmHg in oral nifedipine group. 50% of patients in group A had a blood pressure range of 160 to 169 mmHg. 52% of patients in nifedipine group had a blood pressure range of 170 to 179 mmHg.

Table 4: Diastolic blood pressure distribution of study subjects

Diastolic Blood Pressure	Group-A Labetalol		Group-B Nifedipine		Total 100
	50	%	50	%	
< 110 mmHg	12	24%	14	28%	26%
≥ 110 mmHg	38	76%	36	72%	74%
T= 0.160 Degree of freedom = 104 0.873 > 0.05 Not Significant					

The baseline diastolic blood pressure did not vary significantly in the groups. The mean of the baseline diastolic blood pressure were 114 mmHg and 111 mm Hg in the groups A and B, respectively. 76% and 72% in groups A and B had diastolic blood pressure more than 110 mmHg.

Table 5: Time taken to achieve target blood pressure distribution of study subjects

Time Taken	Group-A Labetalol		Group-B Nifedipine	
	50	%	50	%
15 min	3	6%	2	4%
30 min	8	16%	17	34%
45 min	22	44%	12	24%
60 min	14	28%	11	22%
75 min	3	6%	8	16%
χ 2 = 9.112 Degree of freedom = 6 0.167 > 0.05 No significant difference				

In group A, 22 patients, constituting 44% of the recruited reached the target blood pressure of less than 150/ 100 mmHg in 45 minutes. 14 patients, constituting 28% of group A achieved the target blood pressure range by 60 minutes. In group B, 17 patients, constituting 34% of the recruited reached the target blood pressure of less than 150/100 mmHg in 30 minutes. 12 patients, constituting 24% of group A achieved the target blood pressure range by 45 minutes. The median time taken in group A is 45 minutes and that of group B is 30 minutes. Overall, there is no statistically significant change regarding the time taken to achieve the target blood pressure.

DISCUSSION

Hypertensive emergency in pregnancy is associated with a considerable morbidity and mortality in both maternal and neonatal populations. The primary aim is to reduce the dangerously elevated blood pressure and ameliorate the severity of the disease. The most vulnerable subjects enrolled in the study were primigravida. There is a higher incidence of preeclampsia in the first pregnancy which was consistent with the studies done by Mukherjee S *et al.*[3] and Zulfeena M *et al.*[4] which concluded that the maximum cases were prmigravida. The majority of the patients had gestational age of 34 to 36 weeks which was in accordance with the study done by Zulfeena M *et al*[4] which concluded that the maximum cases had gestational age of 34 to 36 weeks. The mean systolic blood pressure in intravenous labetalol group was 168 mmHg whereas it was 171 mmHg in oral nifedipine group where as The mean of the baseline diastolic blood pressure were 114 mmHg and 111 mmHg in the groups A and B, respectively. The mean systolic blood pressure of the patients enrolled in the labetalol and nifedipine groups in the present study was 171 mmHg and 170 mmHg, respectively and the recruited reached the target blood pressure of less than 150/100 mmHg in 45 minutes in group A in 44% of cases where asthe recruited reached the target blood pressure of less than 150/100 mmHg in 30 minutes in group B in 34% of cases which was similar to the study done by Raheem *et al.*[5] who concluded that both labetalol and nifedipine are equally efficacious in controlling blood pressure where as Vermilion *et al.*[6] concluded that oral nifedipine is superior when compared to labetalol in blood pressure control where as in our study on statistical analysis, there was no significant difference in the time taken for both the drugs to act for reduction in systolic blood pressure.

CONCLUSION

From this study, we can conclude that management of severe pre-eclampsia is in the control of blood pressure, prevention of complications, fetal surveillance and expedition of delivery if indicated and also both the drugs were

found to be safe and effective in the reduction of blood pressure. None of the drugs were associated with any detrimental maternal or fetal outcomes with respect to the anti hypertensive usage. The tolerance of the patients towards both the drugs was similar.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Cunningham F, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CY. Pregnancy hypertension. In: Dashe JS, Hoffman BL, editors. Williams Obstetrics. 23rd ed. NewYork: McGraw-Hill. 2010. p. 706-7.
2. Podymov T, August P. Update on the use of Antihypertensive drugs in pregnancy. Hypertension. 2008;51:960-9.
3. Mukherjee S, Khan S, Jain U, et al. A comparative evaluation of intravenous labetalol versus oral nifedipine for control of severe pregnancy-induced hypertension with low-dose regimen. Int J Med Sci Public Health. 2016; 5(6): 1183.
4. Zulfeen M, Tatapudi R, Sowjanya R. Erratum to "IV labetalol and oral nifedipine in acute control of severe hypertension in pregnancy-A randomized controlled trial" [Eur. J. Obstet. Gynecol. Reprod. Biol. 236 (May) (2019) 46-52]. Eur J Obstet Gynecol Reprod Biol. 2020; 247: 272.
5. Raheem I,Saaid R, Omar S, Tan P. Oran nifedipine versus intravenous labetalol for acute blood pressure control in hypertensive emergencies of pregnancy: a randomised trial. BJOG. 2012;119:78-85. 59.
6. Vermilion ST, Scardo JA, Newman RB, Chauhan SP. A randomized, double blind trial of oral nifedipine and intravenous labetalol in hypertensive emergencies of pregnancy. Am J Obstet Gynecol. 1999;181:858-61.